

Notice of Allowability

Application No.

09/543,679

Applicant(s)

NYCE ET AL.

Examiner

Art Unit

Janet L. Epps-Ford, Ph.D.

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Examiner's Amendment and Interview Summary of 10-14-04.
2. ☒ The allowed claim(s) is/are 92-99, 103, 105, 107 and 108.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 10-26-04
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Janet L. Epps-Ford, Ph.D.
Patent Examiner
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Albert Halluin on 10-26-2004.

The application has been amended as follows:

In the claims:

92. (Currently Amended) An in vivo method of delivering a pharmaceutical composition to a subject comprising administering to the airways of said subject a pharmaceutical composition comprising a respirable or inhalable pharmaceutical composition having a particle size of 0.5 μm to 10 μm in size, comprising at least one antisense oligonucleotide effective to alleviate hyper-responsiveness to adenosine or increased levels of adenosine, ~~or to alleviate bronchoconstriction, asthma, or lung allergy~~ wherein the antisense oligonucleotide is 7 to 60 nucleotides long and contains up to and including about 15% adenosine or less adenosine, pharmaceutically or veterinarily acceptable salts of the oligonucleotide(s), mixtures of the oligonucleotide(s) or their salts.

Claims 106 and 109-115, 120, and 124-125 were cancelled.

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In the first line of the specification the following text was entered:

--This application claims benefit of Provisional Application Nos. 60/059,160, filed September 17, 1997, 60/095,212, filed August 3, 1998; and 60/127,958, filed April 6, 1999.

This application is a continuation-in-part of Serial No. 09/093,972, filed June 9, 1998, now pending, which also claims benefit of 60/059,160; and a continuation-in-part of Serial No. 09/016,464, filed January 30, 1998, now pending; each of which are a continuation-in-part of Serial Nos. 08/472,527, filed June 7, 1995, now US Patent No. 6,025,339, and Serial No. 08/474,497, filed June 7, 1995, now US Patent No. 5,994,315.

This application is also a continuation-in-part of Serial No. 08/757,024, filed June 5, 1997, now US Patent No. 6,040,296, which is a continuation-in-part of Serial No. 08/472,527, filed June 7, 1995, now US Patent No. 5,994,315.

This application is also a continuation of PCT Application Nos. PCT US98/19419, filed September 17, 1998; PCT US99/17712, filed August 3, 1999, and PCT US00/08020, filed March 24, 2000.--

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The abstract of the invention filed on 4/04/2000 was deleted and was replaced by the following abstract on a separate page after the claims:

--ABSTRACT

An in vivo method of selectively delivering a nucleic acid to a target gene or mRNA, comprises the topical administration, e.g. to the respiratory system, of a subject of a therapeutic amount of an oligonucleotide (oligo) that is anti-sense to a mRNA complementary to the gene in an amount effective to reach the target polynucleotide and reducing or inhibiting expression. The composition and formulations are used for prophylactic, preventive and therapeutic treatment of ailments associated with impaired respiration, lung allergy(ies) and/or inflammation and depletion lung surfactant or surfactant hypoproduction, such as pulmonary vasoconstriction, inflammation, allergies, allergic rhinitis, asthma, impeded respiration, lung pain, cystic fibrosis, bronchoconstriction. The treatment of this invention may be administered directly into the respiratory system of a subject so that the agent has direct access to the lungs, in an amount effective to reduce or inhibit the symptoms of the ailment.--

2. The following is an examiner's statement of reasons for allowance: It is noted that although instant Claims 92-99, 103, 105, 107, and 108 are in condition for allowance, the instant claims can be provisionally rejected for Non-statutory Obvious-type Double Patenting over claims 108-122 of copending later filed application 10/758,451. It is noted that the instant application has a filing date of April 4, 2000, and application 10/758,451 was filed January 14, 2004. Since the instant application has an earlier filing date than U.S. application 10/758,451, and is the senior application, as per MPEP § 804 I.B. the instant application will be permitted to go on to issue, and a formal Double Patenting Rejection will be made of record in the child application 10/758,451.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Patent Examiner
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